IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re reissue application of	:	Box: Reissue
Jürgen SPONA et al.	:	Group Art Unit:
Serial No.: Not Yet Issued	:	Examiner:
Filed: Herewith	:	

For: COMPOSITION FOR CONTRACEPTION

DECLARATION UNDER 37 C.F.R. §1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

1. I, Bernd Düsterberg, being duly warned declare that:

2. I am an inventor of the above-identified reissue application.

3. I am an employee of Schering AG, the assignee of the above-identified patent application.

4. A copy of my CV is attached.

5. The above application gives suitable dosages for drospirenone in an oral contraceptive formulation designed for female humans, i.e., (a) 0.25 to 0.3 mg and (b) 0.1 to 0.3 mg.

6. Publications relevant to the conventional dosages for drospirenone or cyproterone acetate for contraception are summarized in the tables below.

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Services as First Class Mail in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on: DECEMBER 4, 2003
Name: SHARON McDANIEL
Signature: Sharon McDaniel

TABLE 1: CONVENTIONAL DOSAGES OF DROSPIRENONE			
PUBLICATION DATE	PUBLICATION	USE/COMMENTS	HUMAN DAILY O.C. DOSE, IN MG.
December 12, 1978	U.S. 4,129,564 (Schering)[1]	Diuretic	20-500 (diuretic) [col. 6, 49-50]
January 7, 1982	DE 3022 337 (Schering)[1]	O.C. or gynecological disorders	0.5-50 (for O.C.) [p. 6, 28-31; claim 3] 5-50 (for gynecological disorders) [p. 7, 1-10; claim 4] Examples 1-3 show 10 or 20 mg dosage units (tablets)
November 22, 1990	EP 318 460 (Schering)[1]	O.C. plus other therapies	0.5-50 1-10 (preferred) [p. 4, 20-21] Examples 1-3 show 10 or 20 mg dosage units (tablets)
1991	Oelkers (1991) Advances in Contraception 7, Suppl. 3, 195-206	O.C.	2 [Abstract]
1991	Oelkers et al (1991) J. of Clinical Endocrinology and Metabolism 73, 837-842 (Schering)[1]	O.C.	2 [p. 838, col. 1, lines 9-13]
1992	Oelkers et al (1992) Acta Endocrinologica 1992: Suppl. 4, p. 71, #97 (Schering)[1]	O.C.	2 [Abstract]
PRIORITY DATE December 1993	U.S. 5,824,667[1] U.S. 5,583,129[1]		Typographical error: 0.1-0.3, or 0.25-0.30
1995	Oelkers et al (1995) J. of Clinical Endocrinology and Metabolism 80, 1816-1821 (Schering)[1]	O.C.	3 [p. 1816, col. 2, line 7]
September 1995	Elstein et al (1995) Zentralblatt für Gynäkologie 117, 559-565	O.C.	2 [p. 562, col. 2, last paragraph]
October 5, 1995	DE 44 11 585 A1[1,2] (English language equivalent is U.S. Pat. No. 5,756,490)	O.C.	1.0-3.0 [col. 5, line 14; claim 3, at col. 8, line 52]

[1] assignee of '667 and '129

[2] inventors include Düsterberg of '667 and '129

TABLE 2: CONVENTIONAL DOSAGES OF CYPROTERONE ACETATE (CPA)			
PUBLICATION DATE	PUBLICATION	USE	HUMAN DAILY DOSE (MG)
1976	Schillinger et al (1976) Arzneim.-Forsch. 26, 2242-5 (Abstract only) (Schering)[1]	O.C.	2 [Title]
1977	Huempel et al (1977) Contraception 16, 199-216 (Abstract only) (Schering)[1]	O.C.	2 [Abstract]
1979	Düsterberg et al (1979) Acta Obstet Gynecol Scand Suppl 88, 27-31(Schering)[1,2]	O.C.	2 [Abstract]
1979	Leis et al (1979) Geburtshilfe Frauenheilkd 39, 54-7 (Abstract only)	O.C.	2 [Title]
1979	Duesterberg et al (1979) Acta Obstet Gynecol Scand Suppl (88), 27-31 (Abstract only) (Schering)[1,2]	O.C.	2 [Title]
1983	Klebe et al (1983) Arch Gynecol 234, 113-120 (Abstract only)	O.C.	2[3][Abstract]
1985	Holdaway et al (1985) Acta Endocrinol 109, 522-529 (Abstract only)	O.C.	2 (O.C.) plus 25-100 (hirsutism) [Abstract]
1985	Kuhl et al (1985) Contraception 30, 467-482 (Abstract only)	O.C.	2 [Abstract]
1986	Larsson-Cohn et al (1986) Acta Obstet Gynecol Scand 65, 125-128 (Abstract)	O.C.	2 [Abstract]
1987	Calaf-Alsina et al (1987) Obstet Gynecol 69, 255-258 (Abstract only)	O.C.	2 [Abstract]
1987	Spona et al (1987) Gynecol Obstet Invest 23, 184-93	O.C.	2 [Abstract]
1990	Jandrain et al (1990)Am J Obstet Gynecol 163, 378-81	O.C.	2 [Abstract]
1991	Oelkers et al (1991) J. of Clinical Endocrinology and Metabolism 73, 837-842 (Schering)[1]	O.C.	1[Abstract; p. 838, col. 2, lines 2-3]
1991	Porcile et al (1991) Fertility and Sterility 55, 877-881 (Abstract only)	O.C.	2 [Abstract]
1992	Oelkers et al (1992) Acta Endocrinologica 1992: Suppl. 4, p. 71,#97(Schering)[1]	O.C.	1 [Abstract]
1993	Scheen et al (1993) Fertility and Sterility 59, 797-802 (Abstract only)	O.C.	2 [Abstract]
1993	Kuhnz et al (1993) Contraception 48, 557-75 (Schering)[1]	O.C.	2 [Abstract]
PRIORITY DATE Dec, 1993	U.S. 5,824,667[1] U.S. 5,583,129[1]		Typographical error: 0.1-0.2
Mar, 1995	EP 640343	O.C.	1 or 2[Title]
October 5, 1995	DE 44 11 585 A1 (Schering)[1,2] (English language equivalent is U.S. Pat. No. 5,756,490)	O.C.	1.0-2.0 [col. 5, line 16; claim 3, at col. 8, line 53 (U.S. Pat)]

[1] assignee of '667 and '129
[2] inventors include Düsterberg of '667 and '129
[3] "low dose standard regimen"

For drospirenone, Table 1 obviously shows to one of ordinary skill in the art as of December 22, 1993 and June 30, 1994, that the values (a) 0.25 to 0.3 mg and (b) 0.1 to 0.3 mg are clearly lower than the known range for use of drospirenone for oral contraception by one order of magnitude, i.e., by obvious misplacement of the decimal point.

Thus, it is obvious to one of ordinary skill in the art, as of the above-mentioned dates, what the correctly intended drospirenone ranges are, i.e., 2.5 to 3.0 mg and 1 to 3 mg, respectively. Accordingly, such a skilled worker reading the patent would know that the actually disclosed ranges for drospirenone are 2.5 to 3.0 mg and 1 to 3 mg, respectively.

The fact that the post-filing reference DE 44 11 585 A1, of which I was an inventor, indicates in several places that the dosage of drospirenone is 1.0 to 3.0 mg (see, e.g., col. 5, line 14, and claim 3, at col. 8, line 51, of the English language equivalent, U.S. Patent No. 5,756,490) further establishes that the intended ranges in the patent to be reissued are, e.g., 1 to 3 mg.

For cyproterone acetate (CPA), this gestagen has been well-known to function as a contraceptive (in combination with an estrogen) for decades. See Table 2, which summarizes some of the many published references, from as long ago as 1976, which disclose a daily dosage of 1 or 2 mg of CPA for oral contraception. Moreover, a commercial oral contraceptive containing CPA in a daily dosage of 2 mg has been marketed, as "Diane 35," in New Zealand, Germany and other European countries since before December, 1993. One of skill in the art as of December 22, 1993 and June 30, 1994, would certainly have known that the CPA dosage range in the patent of 0.1 to 0.2 mg for oral contraception is clearly lower than the known range by one order of magnitude, i.e., by obvious misplacement of the decimal point.

Thus, it is obvious to one of ordinary skill in the art, as of the above-mentioned dates, what the correctly intended CPA range is, i.e., 1 to 2 mg. Accordingly, such a skilled worker reading the patent would know that the actually disclosed range for CPA is 1 to 2 mg.

The post-filing reference DE 44 11 585 A1, of which I was an inventor, also indicates that the dosage of CPA is 1 to 2 mg. This publication further establishes that the intended range in the patent to be reissued is 1 to 2 mg.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

February 11, 2000
Date

Bernd Düsterberg

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Curriculum Vitae

Bernd Düsterberg, Ph.D.

Date of birth:	March 11, 1949
Place of birth:	Berlin

Education:

1968 - 1974:	Free University of Berlin, studies in biology
1973	Diploma in biology, majoring in endocrinology and animal physiology
1974	Doctoral Degree

Professional Career:

1974	Schering AG, Berlin, Academic staff
1974 - 1976	Preclinical development of parenteral and enteral contrast media for roentgenology
1977 - 1985	Preclinical and clinical research concerning the pharmacokinetics of sexual hormones
1981	Certification as a specialist in pharmacology, awarded by DPhG
1986 - 1987	Scientific advisor for fertility and endocrine therapy
1987 - 1996	Clinical Development Fertility control Head of "Contraception II"
since 1997	Head of the department "Medical Affairs"

Memberships:

since 1979	German Pharmacological Society (DPhG)
since 1990	German Society for Endocrinology
since 1993	Society for Obstetrics and Gynecology, Berlin
since 1994	European Society of Contraception

Status: January 2000